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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/531,375	03/21/2000	Auriela Haller	7682-049	7698

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EXAMINER	
SALIMI, ALI REZA	
ART UNIT	**PAPER NUMBER**
1648	18

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/531,375	Haller et al
Examiner	**Art Unit**
A. R. SALMI	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 20, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *17-25* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *17-25* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *16*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Request Continued Examination (RCE)

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/20/2002 has been entered. The supplemental information disclosure (IDS) filed 11/20/2002 is noted. No further response has been received by the Office, hence, the Office Action mailed 6/20/02 is substantially reiterated.

Response to Amendment

This is a response to the amendment A, paper No.13, filed 5/7/02. Claims 1-16 have been canceled. Claims 17-25 have been added and are pending before the examiner.

Claim Rejections - 35 USC § 112

Claims 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record advanced in the previous Office Action mailed 11/7/01. Applicant have submitted new claims and assert that new claims are no longer indefinite and refer to the specification for the "backbone" genes. In addition, applicants assert that the chimeric virus

is both chimeric virus and expression vector. Applicant's argument as part of amendment A, Paper NO. 13, filed 5/7/02 has been considered fully, but they are not persuasive. In the first fold applicants have substituted one set of indefinite claims for another. Applicants interpretation of an expression vector and chimeric virus is misplaced (emphasis added). The chimera of anything means that something is composed of parts that are of different origin and are seemingly incompatible. The expression vector i.e plasmid or a phage is used to introduce specific genes into the genome of an organism, or express a gene in cell milieu wherein a specific immune response maybe massed against the specific gene and not the rest of the vector. Here applicants have formed a chimera of bovine and human parainfluenza virus to induce immune response against the entire parainfluenza chimera and not just the "foreign gene", no where in the specification applicants have expressed a heterologous gene. Applicants are requested to carefully read their own specification. In addition, with regard to reference to teaching of specification and reading the limitations into the claims, applicants are reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The rejection is maintained.

Claim Rejections - 35 USC § 112

Claims 17-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for bovine parainfluenza type 3 (bPIV3) having its surface glycoproteins HN

and F genes being substituted with HN and F glycoproteins of human parainfluenza virus type 3 (hPIV3) , forming a chimeric bPIV3/hPIV3 virus that is utilized in induction of immune response (antibodies only) which happens to exhibit temperature attenuating characteristics, for reasons of record advanced in the previous Office Action mailed 11/7/01. Applicants argue that the induction of antibodies in hamster when injected by bPIV3/hPIV3 virus resulted in production of antibodies and assert that they should be entitled to vaccine limitation for any and all antigens. In addition applicants argue that the specification provides ample guidance for how to make the chimera viruses. Applicant's argument as part of amendment A, Paper NO. 13, filed 5/7/02 has been considered fully, but they are not persuasive. Applicants patent eligibility is determined by the teaching they have provided in the specification and are willing to provide to the public. Here, the claims are broadly drafted which reads on any and all types of chimera. But the specification has limited teaching as stated before and does not provide teaching for any and all chimeras absent undue experimentations. Applicants can not rely on ordinary skilled in the art to enable the full scope of the claimed invention absent adequate teaching. The scope of the claims read on vaccine for HIV and many other viruses, however, the state of the art does not recognize such assertions and absent clear teaching undue experimentations would be required, applicants might dismiss what examiner raises as routine, but the state of the art both at the time of filing and post filing would not dismiss that as routine experimentation. The skill level is rather high in this art, but so are the hurdles facing the artisans, the problems are not as routine as the applicants would have us believe. To date there are no successful vaccine against many many viruses including

parainfluenza or HIV. Applicants own data indicates induction of antibodies, this is not complete protection. There are no challenge studies present, even for parainfluenza. Moreover, with regard to applicants assertion that "The Examiner fails to give reasons for lack of enablement for use of chimeric viruses to express the heterologous sequences" (middle of the page 9 of the response), it must be said it is not so much the failure of the examiner but the failure of the specification. Applicants mistakenly use the term "chimeric virus" and "expression vector" interchangeably, but these terms have distinct meaning in the art as stated above and are not interchangeable, applicants can provide support to the contradictory. Although, there are chimeric viruses in the art that are utilized as expression vectors, but the different regions are distinctly articulated and the regions where a foreign gene might be placed are also articulated, and the foreign gene is expressed in cellular milieu and not the chimera virus, the induction of antibody is against the foreign antigen not the chimera. In other words, the chimeric virus facilitates the expression of a heterologous gene. But such is not the case in the present specification, no where in the specification applicants have taught expression of any heterologous gene. In addition, the previous Office Action clearly pointed out what the specification has taught and what applicants are entitled to. Applicants are only entitled to chimeric bPIV3/hPIV3 wherein bovine parainfluenza type 3 (bPIV3) has its surface glycoproteins HN and F genes substituted with HN and F glycoproteins of human parainfluenza virus type 3 (hPIV3), and the said chimera induced antibody response only (immunogenic response). The rejection is maintained.

Claim Rejections - 35 USC § 102

Claims 17-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Murphy et al (WO 98/53078), for reasons of record advanced in the previous Office Action mailed 11/7/01. Applicants argue that Murphy et al does not specifically describe Kansas-strain and hence the above art is not anticipatory. Applicant's argument as part of amendment A, Paper NO. 13, filed 5/7/02 has been considered fully, but they are not persuasive. The above cited art also does not exclude Kansas-strain either. Applicants direction to 2132.02 are noted, but MPEP says "A genus does not always anticipates a claim.....", however, the MPEP does not say "A genus never anticipates a claim...", in other words the issues should be evaluated on a case by case bases, no where in Murphys' et al teaching they say they want to be excluded of Kansas-strain or be limited to only one strain. The above cited art is a pioneering invention. As such, they are entitled to the broadest possible interpretation. Applicants would appreciate knowing that if they were the first to invent the invention same deference would be warranted to them. Specially given the fact that Bovine parainfluenza Kansas-strain is well known in this art and it is commonly utilized to induce immune response, as evidence see Karron et al, The Journal of Infectious Diseases, 1995, vol. 171, pages 1107-1114. Hence, it can be concluded that Murphys' et al teaching indeed included a well known species i.e. Kansas-strain. The rejection is maintained.

NEW GROUNDS Of REJECTION:

Claim Rejections - 35 USC § 112

Claims 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17, and 23 are vague and indefinite. The intended chimeric virus is ill defined. The boundaries of chimera is not defined, and its intended function is not present. The metes and bounds of the intended heterologous sequences are not defined. It is not clear what genes are being substituted added or deleted? It is not clear whether the invention is directed to a chimeric vector, which means genes from two different types of virus are fused as to form a virus that is capable of expressing a foreign gene, or a general parainfluenza expression vector wherein the vector is capable of expressing foreign antigens. If a chimeric virus is intended then the claim should clearly indicate which genes of the two intended viruses form the chimeric virus. And if a bovine parainfluenza virus is intended to be utilized as a general expression vector then the claim should clearly indicate which genes are being deleted and where a heterologous gene is being inserted. Moreover, the intended nucleotide sequence is not defined. What genes are being added or substituted to the virus genome? Is M gene being substituted? This affects the dependent claims.

Claim 18, and 21 are vague and indefinite the intended sequences are not defined. Is P sequence intended?

Claim 22 is indefinite for recitation of "mutations or modifications", the intended "mutations or modifications" are not defined, moreover, the term "modification" is a relative term subject to varied interpretations. What is/are the mutations that causes the formulation to be expressing attenuated phenotype(s)? What are the genes that form the "backbone"? Moreover, the claim is indefinite for recitation of "enhanced antigenicity", this is a relative terminology, how is the "enhancement" determined?

In addition, claim 23 recites the limitation "said backbone" in line 4. There is insufficient antecedent basis for this limitation in the claim. Moreover, What are the genes that form the "backbone"?

Claims 24, and 25 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. There is no "heterologous sequence" in claim 20.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

12/12/2002

ALI R. SALIMI
PRIMARY EXAMINER